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Application No. 10/785349
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Amendment
Attorney Docket No. S63.2N-9776-US02

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Remarks

This Communication is in response to the Office Action dated August 1, 2006. In the Office Action claim 1 was rejected under 35 USC 102(e) as being anticipated by Mikus et al. (US 2002/0035391); claims 2, 6, and 7 were rejected under 35 USC 103(a) as being unpatentable over Mikus et al. in view of Boylan et al. (US 2003/0187497); claims 4 and 5 were rejected under 35 USC 103(a) as being unpatentable over Mikus et al. in view of Guglielmi et al (US 6,011,995); and claim 8 is rejected under 35 USC 103(a) as being unpatentable over Mikus et al. in view of Boylan et al. and in further view of Guglielmi et al.

For the reasons presented herein, Applicants have traversed the rejections and assert that the claims are in condition for allowance.

The following comments are presented with paragraph numbers and headings corresponding to those of the Office Action.

35 USC 102(e)

In the Office Action claim 1, was rejected under 35 USC 102(e) as being anticipated by Mikus et al. (2002/0035391). Instant independent claim 1 recites "an expandable stent being disposed about at least a portion of the expandable region." The Office Action asserts that Mikus et al discloses "a catheter ... [with a] distal portion having an expandable region [the mesh basket 14], an expandable stent being disposed about at least a portion of the expandable region." The Office Action further asserts that the term "about" has been interpreted broadly and thus, according to the Merriam-Webster Dictionary, means "reasonably close to" or "in the vicinity."

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Applicants disagree with both assertions. Under MPEP 2111 “pending claims must be given their broadest reasonable interpretation consistent with the specification” and that “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” MPEP 2111.01 explains further that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e. as of the effective filing date of the patent application” and that “[i]t is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the “ordinary” and “customary” meaning of the terms in the claims.” In addition, the recent case by the Federal Circuit, *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) states that “a person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.”

When the specification of the instant application is referenced, the meaning of “disposed about” is clear. In reference to Fig. 1, the specification states that “[c]atheter 100 includes an inner member 104 *about which stent 114 is disposed*” (page 4, lines 18-19). Other references to one portion of the catheter assembly being disposed about another portion of the catheter assembly are: the “[o]uter member 106 is *disposed about* inner member 104” and, if a balloon expandable stent is used, the “balloon 108 is *disposed about* inner member 104” with the “[s]tent 114 ... *disposed about* balloon 108” (page 4, lines 21-22 and page 5, lines 2-4, *see also* page 5, line 13 and lines 30-32 and page 6, lines 1-2 for other examples of the use of the term “disposed about”). An annotated copy of Fig. 4, a cross-section of the catheter, is provided below as a pictorial definition of “disposed about,” as used in the instant application.

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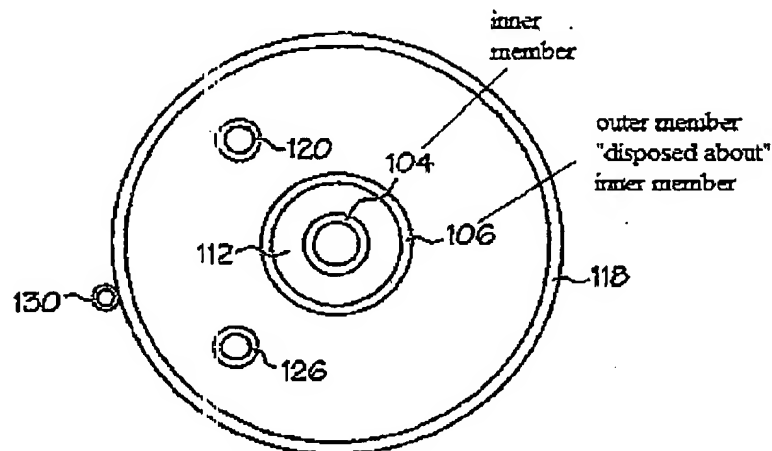


FIG. 4

As shown above, FIG. 4 illustrates what is meant by the statement in the specification that "[o]uter member 106 is *disposed about* inner member 104" (page 4, lines 21-22). With the specification of the instant application in mind, Applicants assert that since the stent in Mikus is positioned *a distance away from* the expandable region, i.e. the mesh basket 14, the stent is not "disposed about" the mesh basket 14, as that term is used in the instant application.

The expandable region in Mikus is a mesh basket (14) that is expanded by pushing the catheter outer shaft distally over the catheter inner shaft (see [0032]). The stent is positioned a distance away from the mesh basket (14). Mikus states that "[t]he stent is best placed ... downstream of the bladder neck sphincter" so "the distance between the anchor and stent [is] chosen and controlled during manufacture to approximate the desired distance between

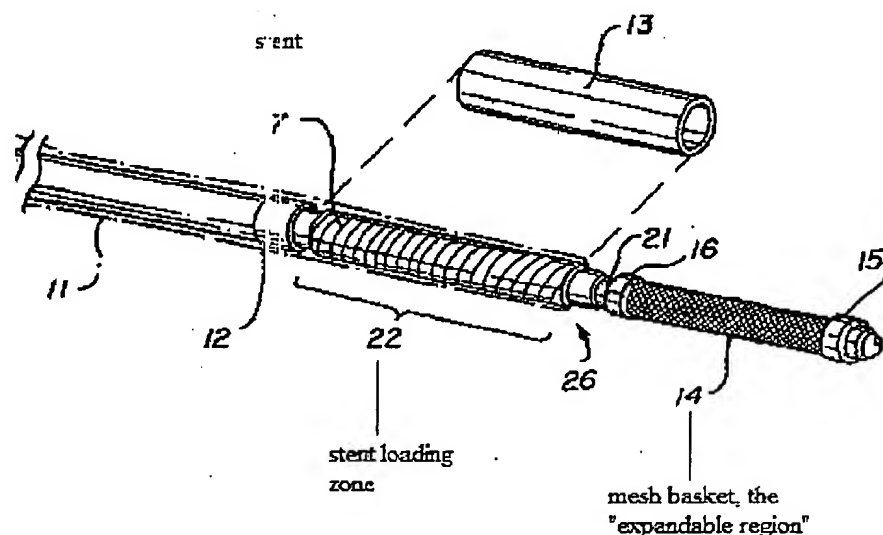
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the bottom of the bladder and the desired release point for the stent at a location downstream of the bladder neck sphincter" (see [0029]). Mikus further states that "[t]he proximal face of the now toroidal mesh basket [i.e. after the mesh basket has been expanded] is seated against the bladder neck sphincter and the *distance between the stent and the mesh basket* is large enough to ensure that the stent is not within the lumen of the bladder neck sphincter, so that it can not interfere with normal operation of the bladder neck sphincter" (see [0034]). Figure 5, the distal portion of which is provided below, shows the separation of the mesh basket (14), which is in an unexpanded state, and the stent (7) which is on the stent loading zone (22). In Figs. 6 and 7 of Mikus, with the distal portion of Fig. 7 provided below, the mesh basket (14), is in an expanded state.

FIG. 5

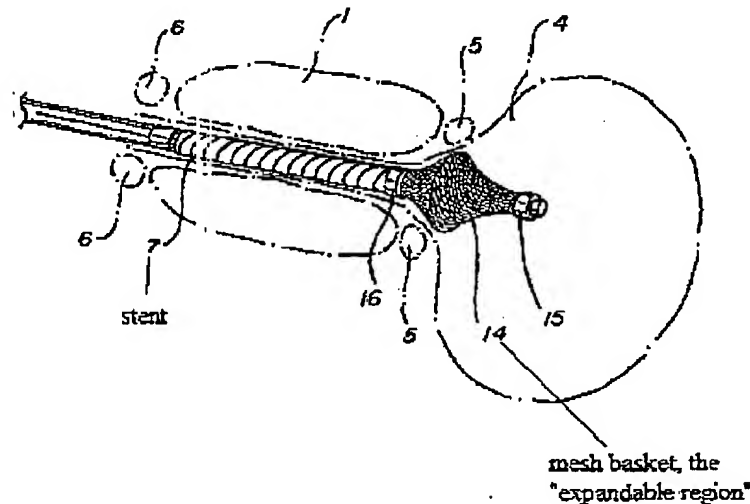


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FIG. 7



Based on the figures and specification of Mikus, Applicants assert that a cross-sectional view of either Figs. 5 or 7, similar to that of Fig. 4 of the instant application, does not show "an expandable stent being *disposed about* at least a portion of the expandable region," as recited in instant independent claim 1. In addition, Mikus does not teach or suggest "delivering the stent to the desired location by expanding the expandable region from an unexpanded diameter to an expanded diameter," as recited in instant independent claim 1 since the stent (7) of Mikus is not disposed about any portion of the mesh basket (14), i.e. the expandable region. For at least these reasons, Mikus does not teach or suggest all the elements of instant independent claim 1. Applicants request withdrawal of the rejection and assert that claim 1 is in condition for allowance.

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35 USC 103(a)

In the Office action claims 2, 6 and 7 were rejected as being unpatentable over Mikus et al. in view of Boylan et al (2002/0187497). Claim 2 depends upon independent claim 1 and claim 7 depends upon independent claim 6. Both independent claims 1 and 6 recite "a stent ... disposed about at least a portion of an expandable region."

As discussed above, Mikus does not teach or suggest all of the elements of instant independent claim 1 or 6, namely, "a stent ... disposed about at least a portion of an expandable region." The proposed addition of the stent made of steel alloys of Boylan does nothing to address the failure of Mikus to teach or suggest all of the elements of instant claims 2, 6 and 7. Applicant request withdrawal of the rejection and assert that claims 2, 6 and 7 are in condition for allowance.

In the Office Action, claims 4 and 5 were rejected under 35 USC 103(a) as being unpatentable over Mikus et al in view of Guglielmi et al. (6,011,995). Claims 4 and 5 are dependent upon instant independent claim 1, which recites "a stent ... disposed about at least a portion of an expandable region." As discussed above, Mikus does not teach or suggest all of the elements of instant independent claim 1. The proposed addition of the contrasting agent of Guglielmi to Mikus does nothing to address the failure of Mikus to teach or suggest all of the elements of instant dependent claims 4 and 5. Applicants request withdrawal of the rejection and assert that dependent claims 4 and 5 are in condition for allowance.

In the Office Action, claim 8 was rejected under 35 USC 103(a) as being unpatentable over Mikus et al in view of Boylan et al and in further view of Guglielmi et al. Claim 8 is dependent upon independent claim 6, which recites "a stent ... disposed about at least a portion of an expandable region." The proposed addition of the stent made of steel alloys of

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Boylan and the contrasting agent of Guglielmi does nothing to address the failure of Mikus to teach or suggest all the elements of independent claim 6, from which claim 8 depends.

Applicants request withdrawal of the rejection and assert that dependent claim 8 is in condition for allowance.

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Conclusion

In light of the above comments, claims 1-2, and 4-8 are believed to be in condition for allowance. Notification to that effect is respectfully requested.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: October 16, 2006

By: _____

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